

(i) Payment adjustments are effective beginning 30 days after the publication of HCFA's determinations in the FEDERAL REGISTER.

§ 416.190 Who may request a review.

Any party who is able to furnish the information required in § 416.195 may request that HCFA review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act with respect to an IOL that meets the definition of a new technology IOL in § 416.180.

§ 416.195 A request to review.

(a) *Content of a request.* The request must include all of the following information:

- (1) The name of the manufacturer, the model number, and the trade name of the IOL.
- (2) A copy of the FDA's summary of the IOL's safety and effectiveness.
- (3) A copy of the labeling claims of specific clinical advantages approved by the FDA for the IOL.
- (4) A copy of the IOL's original FDA approval notification.
- (5) Reports of modifications made after the original FDA approval.
- (6) Other information that HCFA finds necessary for identification of the IOL.

(b) *Confidential information.* To the extent that information received from an IOL manufacturer can reasonably be characterized as a trade secret or as privileged or confidential commercial or financial information, HCFA maintains the confidentiality of the information and protects it from disclosure not otherwise authorized or required by Federal law as allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905).

§ 416.200 Application of the payment adjustment.

(a) HCFA recognizes the IOL(s) that define a new technology subset for purposes of this subpart as belonging to the class of new technology IOLs for a period of 5 years effective from the date that HCFA recognizes the first

new technology IOL for a payment adjustment.

(b) Any IOL that HCFA subsequently recognizes as belonging to a new technology subset receives the new technology payment adjustment for the remainder of the 5-year period established with HCFA's recognition of the first IOL in the subset.

(c) Beginning 5 years after the effective date of HCFA's initial recognition of a new technology subset, payment adjustments cease for all IOLs that HCFA designates as belonging to that subset and payment reverts to the standard payment rate set under section 1833(i)(2)(A)(iii) of the Act for IOL insertion procedures performed in ASCs.

(d) ASCs that furnish an IOL designated by HCFA as belonging to the class of new technology IOLs must submit claims using specific billing codes to receive the new technology IOL payment adjustment.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

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